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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,401

01/04/2006

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EXAMINER

GETZOW, SCOTT M

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

12/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,401	Applicant(s) LUDLOW ET AL.	
	Examiner Scott M. Getzow	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-35 and 44-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-10 and 13-20 is/are allowed.
- 6) ☒ Claim(s) 21-35 and 44-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/21/08, 9/18/08</u> . | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 103

1. Claims 21-35,44-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freed et al (5,891,185) in view of Sanders (5,897,579).

In addition to the comments made in the previous office action, Freed teaches a device which can send stimulating signals to each of a plurality of electrodes, see column 6. Freed also teaches that simultaneous or sequential stimulation can be provided, col. 7:10+, and that a weak muscle contraction signal evidencing the patient's attempt to swallow can be generated, col. 7:30+, and sensors which can be used to allow for feedback control of the stimulation, col. 7:24. As mentioned previously, the electrodes of Freed are external electrodes. Sanders teaches the use of implanted electrodes, as well as a implanted stimulator. To use implanted electrodes with the device of Freed would have been obvious since such would be the combination of known prior art elements yielding a predictable result. Clearly, the Freed device is used to stimulate the muscles and other structures *under* the skin of the patient. To use implanted electrodes to so stimulate the underlying tissue would not ruin the operability of the Freed device. Further, the signals produced could be complex, since that term is very broad and the signals produced by Freed can overlap one another when stimulating different muscles. Also, the term 'switch' is also very broad. Both Freed and Sanders show elements that can be used to control the pulse generator, see for example Freed, column 4:45+. Still further, column 4 of Freed teaches that various frequencies can be used for the stimulation, such as between 4 and 80 Hz.

Allowable Subject Matter

2. Claims 1-10,13-20 are allowed.
3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Applicant's remarks have been considered, however the above rejections are still deemed to be proper. It is the examiner's position that the all of the *structure* of the above apparatus claims are encompassed by the combination of Freed and Sanders. Applicant's apparatus claims set forth *intended uses* that *could* be performed by the structure of Freed and Sanders, if desired. In fact, many of the apparatus claims could 'read on' a wide variety of implantable stimulators, such as spinal cord stimulators, neural stimulators, etc.

Art Unit: 3762

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott M. Getzow whose telephone number is (571) 272-4946. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Scott M. Getzow/
Primary Examiner, Art Unit 3762